HFI-35

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2771

April 25, 2000

WARNING LETTER
CIN-WL 00-2658

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Mr. Howard A. Stritzel
Stritzel Farm
34990 Capel Road
Columbia Station, Ohio 44028

Dear Mr. Stritzel:

The U. S. Food and Drug Administration (FDA) was informed by the USDA that tissue from a dairy cow identified with the back tag number: 31CT0828, and slaughtered on or around January 4, 2000 was found to contain an illegal drug residue. The USDA laboratory's analytical report #271794, shows that the muscle tissue of the referenced animal contained 1.90 ppm Sulfadimethoxine. The established tolerance level for this drug in cows intended for slaughter as human food is 0.1 ppm. This cow was offered for slaughter as food in violation of Sections 402 (a)(2)(C) (ii), and 402 (a)(4) and Section 501 (a)(5) of the Federal Food, Drug, and Cosmetic Act (FD&C Act). An investigation at your dairy operation conducted by our investigator on March 16, 2000 and March 20,2000, determined that this cow belonged to you.

A food is adulterated under Section 402 (a)(2)(C) (ii) of the Act, if it contains a new animal drug which is unsafe within the meaning of Section 512 and Section 402 (a)(4) if the food has been held under insanitary conditions whereby it may have been rendered injurious to health. As it applies in this instance, "insanitary conditions", refers to your lack of records for animals which you medicate. Consequently, you held an animal, which was ultimately offered for sale for food, under conditions which are so inadequate that a medicated animal bearing possibly harmful drug residues was likely to enter the food supply. A drug is adulterated under Section 501 (a)(5) if it is administered in a manner other than in accordance with the directions specified in the labeling, thereby making it unsafe within the meaning of Section 512(a)(1)(B).

The FD&C Act prohibits adulterated food from being introduced or delivered for introduction into interstate commerce. The Federal Courts have also held that animals intended for slaughter are food. Therefore, animals which contain illegal levels of drug residues are adulterated food when intended for, or bought for slaughter.

In addition, the FD&C Act is a strict liability statue, which requires that anyone in a position of authority and power to prevent violations of the ACT take all reasonable steps to do so. The failure to act to prevent unlawful sales violates the law even when no intent to do any wrongful act existed.

Please notify this office within fifteen (15) working days of the receipt of this letter of the specific steps that you have taken to correct the noted violations. Your response should include an explanation of each step being taken to prevent the recurrence of similar violations in future. If your corrective action can not be completed within 15 working days, please state the reason for the delay, and the time frame within which the necessary corrections will be completed.

Failure to promptly implement adequate corrections may result in further regulatory action without such as seizure and/or injunction, without additional notice.

Your response should be directed to the U. S. Food and Drug Administration, Cincinnati District Office, 6751 Steger Drive, Cincinnati, Ohio 45237-3097, ATTN: David C. Radle, Tissue Residue Monitor.

Sincerely,

Henry L. Fielden
District Director
Cincinnati District